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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/533,749	05/10/2005	Lawrence Allan Lynn		7983

7590 06/18/2009

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EXAMINER	
MEHTA, BHISMA	
ART UNIT	PAPER NUMBER
3767	

MAIL DATE	DELIVERY MODE
06/18/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/533,749	LYNN, LAWRENCE ALLAN	
	Examiner	Art Unit	
	BHISMA MEHTA	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 March 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *31-36* is/are allowed.

6)☒ Claim(s) *1-29* is/are rejected.

7)☒ Claim(s) *30* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Objections

1. Claims 8 and 30 are objected to because of the following informalities: In claim 18, it is unclear if the "at least one volume reducing element" in line 3 is referring to the "at least one volume reducing element" in lines 14-15 of claim 8 or a different at least one volume reducing element. It is suggested that the wording of "at least one volume reducing element" be replaced with "said at least one volume reducing element". In claim 30, it is unclear if the "at least one proximal terminal" in lines 9-10 is referring to the "at least one proximal terminal" in line 8 of claim 30 or a different at least one proximal terminal. It is suggested that the wording of "at least one proximal terminal" be replaced with "said at least one proximal terminal". Appropriate correction is required.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 29 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 29, it is unclear which volume reducer from the plurality of volume reducers recited in line 13 of claim 29 is being referred to with regards to the use of “the volume reducer” in line 16.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 1-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ash (U.S. Patent No. 6,958,049) in view of Bierman (U.S. Patent No. 5,318,546). Ash discloses a catheter-flushing system having a tubing system comprising a single extension tube (14) and a volume reduction system (20). The single extension tube (14) is in fluid connection with an indwelling portion of a catheter (10). In lines 9-28 of column 6, Ash discloses that the tubing system or catheters can include single or double lumens. The tubing system defines an internal volume and at least one proximal terminal including a seal (28). The proximal terminal has intermittent connection with an external fluid source or a flush solution such as saline (lines 14-16 of column 5) or a mixture of a diluent and at least one of an anticoagulant and an antimicrobial agent (lines 25-36 of column 7). Activation of the volume reducer is capable of reducing the volume within the tubing system by a plurality of discrete volumes. Ash discloses the system substantially as claimed. However, Ash is silent on the catheter-flushing system having at least one volume reduction comprised of at least one of a plurality of volume reducers, a single volume reducer having a plurality of levels of reduction, and a single volume reducer comprised of a plurality of multiple elements. Bierman discloses a single extension tube (18) with a volume reduction system comprised of a plurality of

volume reducers (20) or a single volume reducer (22) having a plurality of levels of reduction (42) or a single volume reducer (22) having a plurality of multiple elements or clamps (20) where the volume reduction system is used to control fluid flow in the tube. It would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute the volume reduction system of Ash with the volume reduction system as taught by Bierman as a mere substitution of one type of volume reduction system and also because the reduction system of Bierman allows for better control of the fluid flow in the tube (lines 29-47 of column 10).

As to claim 8, the patient mounted system includes a single extension tube (14) having a distal end connectable to a catheter (10), an internal open space defining a variable internal volume, and a lumen extending through the tube. The volume reducer comprises at least one volume reducing element (20) mounted within the system where the element comprise a clamp. The volume reducer can be considered to be a pinch clamp and also defines opposing elongated opposing surfaces. The tube (14) has a variable internal diameter (see lines 16-18 of column 6) and includes an enlarged portion as seen in Figure 1. Ash discloses the system substantially as claimed. However, Ash is silent on the system having a plurality of volume reducers. Bierman discloses a single extension tube (18) with a plurality of volume reducers comprising of volume reducing elements or clamps (20) which are used to control fluid flow in the tube. It would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute the volume reducer of Ash with the plurality of volume reducers as taught by Bierman as the plurality of volume reducers of Bierman allows for

better control of the fluid flow in the tube (lines 29-47 of column 10).

As to claim 19, the medical device comprises a fluid-lock system with a distal portion which defines an indwelling portion and a single extension tube (14) having an internal space defining an internal volume. The medical device also has a volume reducer (20) for engaging the system and for progressively reducing the volume of flush solution contained within the internal space by facilitating movement of at least sequential portions of the flush solution into a blood vessel. Ash discloses the system substantially as claimed. However, Ash is silent on the medical device having a plurality of volume reducers. Bierman discloses a single extension tube (18) with a plurality of volume reducers (20) which are used to control fluid flow in the tube. At least one volume reducer is configured to reduce the volume of the single extension tube a first time and at least a second volume reducer is configured to reduce the volume a second time such that the second residual volume is less than the first residual volume. It would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute the volume reducer of Ash with the plurality of volume reducers as taught by Bierman as the plurality of volume reducers of Bierman allows for better control of the fluid flow in the tube (lines 29-47 of column 10).

As to claims 27 and 29, the system includes a reservoir comprising a single extension tube (14) and a volume reducer (20) configured for engaging sequential portions of the reservoir. Ash discloses the system substantially as claimed. However, Ash is silent on the system having a plurality of volume reducers. Bierman discloses a single extension tube (18) with a plurality of volume reducers (20) which are used to

control fluid flow in the tube. At least one volume reducer is configured to reduce the volume of the single extension tube a first time and at least a second volume reducer is configured to reduce the volume a second time such that the second residual volume is less than the first residual volume. It would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute the volume reducer of Ash with the plurality of volume reducers as taught by Bierman as the plurality of volume reducers of Bierman allows for better control of the fluid flow in the tube (lines 29-47 of column 10).

Allowable Subject Matter

6. Claims 31-36 are allowed.

7. The following is a statement of reasons for the indication of allowable subject matter: As to claims 30, 31, and 35, the method for intermittently flushing the lumen of an indwelling catheter including the step of reducing the volume of the extension tube a first time to define a first residual volume and a second time to define a second residual volume where the second residual volume is less than the first residual volume in addition to the other claimed steps of the method was not found in the prior art. As to claim 32, the method for intermittently flushing the lumen of an indwelling catheter including the step of reducing the volume of the extension tube a first time to define a first residual volume where the first residual volume is less than the initial volume of flush solution in addition to the other claimed steps of the method was not found in the prior art.

Response to Arguments

8. Applicant's arguments filed March 16 2009 have been fully considered but they are not persuasive. In response to applicant's argument in line7 of page 23 to line 13 of page 25 that there is no suggestion to combine the references (that Bierman teaches away from the present invention), the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, both Ash and Bierman disclose catheter-flushing systems with a single extension tube in fluid communication with an indwelling catheter and further with a volume reduction system. The teaching of providing the volume reduction system of Bierman to the catheter-flushing system of Ash is a mere substitution of one type of volume reduction system for another where both the volume reduction system of Ash and the volume reduction system of Bierman can be used to stop the flow of fluid in the extension tube from a fluid source (see lines 49-58 of column 3 and lines 29-47 of column 10 of Bierman).

9. Applicant's arguments, see line 13 of page 25 to line 15 of page 26, filed March 16 200, with respect to claims 30-36 have been fully considered and are persuasive. The rejection of claims 30-36 has been withdrawn.

Conclusion

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BHISMA MEHTA whose telephone number is (571)272-3383. The examiner can normally be reached on Monday through Friday, 7:30 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on 571-272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Bhisma Mehta/
Examiner, Art Unit 3767
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